



The Chemical Company

Agricultural Products Division

April 8, 2010

Mr. Tony Kish (Product Manager 22)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Application for Registration of BAS 500 20 F Fungicide
Active Ingredient: Pyraclostrobin
Use in Corn (field corn, pop corn and seed production corn)

Dear Mr. Kish:

This letter conveys BASF's application for registration of **BAS 500 20 F Fungicide**, a new encapsulated formulation containing pyraclostrobin for use in corn (including field corn, pop corn and seed production corn). In a meeting with EPA on March 25, 2009, BASF explained the concept supporting the need for this unique formulation, comparing the proposed use pattern to the already registered use as labeled for Headline® Fungicide (7969-186), an emulsifiable concentrate formulation. A copy of the meeting summary is enclosed, detailing the proposed use pattern and rationale for generating field residue and soil dissipation bridging data in lieu of conducting conventional studies typically required for registration of an encapsulated formulation.

Please note that, as a follow-up action from the above-mentioned meeting, BASF submitted a proposed protocol for conducting a "wash-off" study for EFED review in a submission dated April 30, 2009; a replacement protocol was then submitted on May 27, 2009. In a letter dated August 9, 2009, EPA responded that the initial protocol was found to be acceptable, but EFED was concerned that it did not "address the dissipation/release rate of the active ingredient from the wash-off encapsulated material that will be deposited onto the soil. They also believed that actual mechanized ground spray (rather than a surrogate for it) should be used to apply the test product." The replacement protocol was not reviewed as it was considered a separate PRIA action. Due to time constraints, BASF initiated the study in June 2009 with EFED's concerns already addressed as follows:

- The original plan was to conduct the study at BASF's field test site (outdoors) and use the irrigation system there to provide a simulated rain. However, we later learned that the water source is pond water containing significant organic and clay content that would bind with the active ingredient and therefore interfere with analysis. While there is a well water source at the site, it is only available for use at a couple of locations where herbicide carryover would likely not permit corn to germinate and grow. After further investigation, it became apparent that the only option that could provide reliable data was conducting the study in a growth chamber in our greenhouse. While there are limitations associated with conducting the study indoors, BASF believes this scenario mimics a

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worse case scenario due to the controlled environment of the indoor setting (prompting the need for the replacement protocol). In addition, EFED's request for using mechanized spray equipment could be satisfied, employing a mechanized spray chamber, with the ability to collect the wash-off water in trays placed beneath the plant canopy. Thus, both the corn leaves and wash-off water could be analyzed for residues of pyraclostrobin.

- BASF had already planned a separate study to investigate dissipation/release rate of the active ingredient from the wash-off encapsulated material that would be deposited onto the soil. While BASF originally proposed conducting a lab-scale soil-release rate study to evaluate the behavior of the encapsulated pyraclostrobin in soil, we decided to conduct a dissipation bridging scenario under actual field conditions to obtain a realistic picture of the potential dissipation vs. the already registered pyraclostrobin-containing end-use formulations. The results provided here pertain to the analysis of soil samples up to 120 days following application (using the proposed application rate of 0.1 lb ai/A), showing no significant difference in the dissipation kinetics of pyraclostrobin due to formulation type.

The following items are enclosed in support of this application:

1. Completed Application for Registration form (8570-1) for BAS 500 20 F Fungicide
2. Completed Certification with Respect to Citation of Data form (8570-34) for BAS 500 F Fungicide, Pyraclostrobin Technical (EPA Reg. No. 7969-185) and Pyraclostrobin Crystalline (EPA Reg. No. 7969-258)
3. Transmittal document
4. Proposed Confidential Statement of Formula for BAS 500 20 F Fungicide (basic and alternate)
5. Proposed product label for BAS 500 20 F in corn (field corn, pop corn and seed production corn)
6. Data matrix for the proposed end-use product, BAS 500 20 F (both internal use and public use copies)
7. Data matrix for the active ingredient Pyraclostrobin Technical, EPA Registration No. 7969-185 (both internal use and public use copies)
8. Data matrix for the active ingredient Pyraclostrobin Crystalline, EPA Registration No. 7969-258 (both internal use and public use copies)
9. Copy of e-mail correspondence from EPA confirming BASF's payment of the associated PRIA fee (\$11,424.00, category R320)
10. Document titled "Pyraclostrobin, Proposed Early Spray Formulation and <2 GPS Application Concepts, Meeting Summary March 25, 2009"
11. BASF's initial and revised protocol titled "The Wash-Off of Encapsulated Pyraclostrobin (BAS 500 F) from Corn Plants"
12. EPA's letter to BASF in response to the protocol (#11 above), dated August 6, 2009

Under the current electronic guidelines, BASF Corporation is submitting all administrative documents and scientific reports for this submission exclusively in electronic (XML) format in lieu of paper copies. MRID numbers are already assigned for scientific reports.



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As agreed by EPA during the meeting of March 25, 2009 (above-listed item #10), BASF generated residue data in corn forage only, using a single application rate of 0.1 lb ai/A, resulting in residues well within the current established tolerance of pyraclostrobin in corn forage. Please note that the data generated to evaluate the residue behavior of this encapsulated formulation in corn forage was conducted using the precursor formulation, BAS 500 18 F, containing the same amount of active ingredient as BAS 500 20 F. A detailed comparison of the composition of these two formulations is provided in the enclosed document titled "Minor Change Reasoning."

BASF wishes to meet with EPA as a follow-up to the meeting of March 25, 2009, to review the results of the data generated and actions taken in support of the registration of this proposed formulation. Separate correspondence will follow to request this meeting.

In the meanwhile, if you have any questions or need further information, please contact me directly at (919) 547-2983, or by e-mail at charlotte.sanson@basf.com.

Best regards,
BASF Corporation
Agricultural Solutions

A handwritten signature in cursive script, reading "Charlotte A. Sanson".

Charlotte A. Sanson
Product Registration Manager

enc.

NVA 2010-04-373-0037

Vol. No.	OPPTS No.	EPA GLN	Study References	MRID No.
1	n/a	n/a	Administrative Documents	No Data
2	830.1550 830.1600 830.1650 870.1670 830.1700 830.1750	61 & 62 series	Arago L. BAS 500 20 F: Product identity, composition, and analysis. March 29, 2010. BASF Reg. Doc. # 2010/7008252. 4 pages with a <u>Confidential Appendix</u> of 121 pages.	48037301
3	830.6302 830.6303 830.6304 830.6315 830.6317 830.6320 830.7000 830.7100 830.7300	63 series	Kroehl T. Physical and chemical properties of BAS 500 20 F (Pyraclostrobin 250 g/L CS) including accelerated storage stability for up to 14 days at 54°C. March 12, 2010. BASF Reg. Doc. # 2010/1026291. 19 pages.	48037302
4	830.6314	63-14	Yacoub R. BAS 500 20/21 F: Determination of oxidation/reduction. April 07, 2010. BASF Reg. Doc. # 2010/7008108. 13 pages.	48037303
5	830.6316	63-16	Fischer S. Evaluation of physical and chemical properties according to Directive 94/37/EC (Regulation (EC) No 440/2008). November 12, 2009. BASF Reg. Doc. # 2009/1099049. 11 pages.	48037304
6	830.1800	63-18	Daum A. Validation of the analytical method AFL0795/01: Determination of total active ingredient Pyraclostrobin (Reg.No. 304 428) in the capsulated formulation (CS) BAS 500 20 F by HPLC. March 11, 2010. BASF Reg. Doc. # 2010/1025749. 22 pages.	48037305
7	Supplemental		Rahn R.T. BAS 500 20 F: Minor change reasoning. March 22, 2010. BASF Reg. Doc. # 2010/1036109. 4 pages.	48037306
8	870.1100	81-1	Cords S.-M., Nehrbass T. BAS 500 20 F - Acute oral toxicity study in rats. November 23, 2009. BASF Reg. Doc. # 2009/1032612. 25 pages.	48037307
9	870.1200	81-2	Cords S.-M., Nehrbass T. BAS 500 20 F - Acute dermal toxicity study in rats. November 23, 2009. BASF Reg. Doc. # 2009/1032613. 26 pages.	48037308

Vol. No.	OPPTS No.	EPA GLN	Study References	MRID No.
10	870.1300	81-3	Wittmer E., Mellert W. BAS 500 20 F - Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure (head-nose only) (Including amendment no. 1). March 23, 2010. BASF Reg. Doc. # 2010/7008261. 59 pages.	48037309
11	870.2400	81-4	Wareing B. BAS 500 20 F - Acute eye irritation in rabbits. January 22, 2010. BASF Reg. Doc. # 2010/1007153. 23 pages.	48037311
12	870.2500	81-5	Wareing B. BAS 500 20 F - Acute dermal irritation / corrosion in rabbits. January 22, 2010. BASF Reg. Doc. # 2010/1007152. 22 pages.	48037310
13	870.2600	81-6	Remmele M., Landsiedel R. BAS 500 20 F - BUEHLER test in guinea pigs. January 21, 2010. BASF Reg. Doc. # 2010/1007151. 30 pages.	48037312
14	Supplemental		Singh M. The wash-off of encapsulated Pyraclostrobin (BAS 500 F) from corn plants. April 06, 2010. BASF Reg. Doc. # 2010/7008264. 26 pages.	48037313
15	Supplemental		Warren R. Comparison of Pyraclostrobin (BAS 500 F) field soil dissipation endpoints from North American trials with EC, WG, and CS formulations. March 26, 2010. BASF Reg. Doc. # 2010/7008184. 35 pages.	48037314
16	860.1500	171-4	Dyk M.M. Magnitude of Pyraclostrobin residues in field corn forage following a single application of BAS 500 18 F in support of registration of BAS 500 20F. April 06, 2010. BASF Reg. Doc. # 2010/7008268. 53 pages.	48037315